

CHILDRENS ROBITUSSIN COUGH AND CHEST CONGESTION DM- dextromethorphan hydrobromide, guaifenesin liquid
Richmond Division of Wyeth

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CHILDREN'S ROBITUSSIN® COUGH AND CHEST CONGESTION DM

Drug Facts

<i>Active ingredients (in each 5 ml)</i>	<i>Purposes</i>
Dextromethorphan HBr, USP 5 mg	Cough suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- do not take more than 6 doses in any 24-hour period

age	dose
children under 4 years	do not use
children 4 to under 6 years	5 ml every 4 hours
children 6 to under 12 years	10 ml every 4 hours
adults and children 12 years and over	20 ml every 4 hours

Other information

- **each 5 ml contains:** sodium 3 mg

- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, artificial flavor, FD&C blue no. 1, FD&C red no. 40, glycerin, natural flavor, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

For most recent product information, **visit www.robitussin.com**

Distributed by:

Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

Children's

Robitussin®

AGES 4 & OVER

**Cough & Chest
Congestion**

DM

DEXTROMETHORPHAN HBr

(Cough Suppressant)

GUAIFENESIN (Expectorant)

Alcohol-Free

4 FL OZ (118 ml)

**Packaged with Tamper-Evident bottle cap.
Do Not Use if breakable ring is separated or missing.**

Active ingredients (in each 5 ml): Dextromethorphan HBr, USP 5 mg; Guaifenesin, USP 100 mg

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AGES 4 & OVER

**Cough & Chest
Congestion**

DM

**DEXTROMETHORPHAN HBr
(Cough Suppressant)
GUAIFENESIN (Expectorant)**

Alcohol-Free 4 FL OZ (118 ml)

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adults and children 12 years and over	20 ml every 4 hours

Distributed by: Pfizer
Madison, NJ 07940 USA
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LOT:
EXP:

PAA078167

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

NEW

Dosing

Information

**Children's
Robitussin®**

NOW FOR AGES 4 & OVER

**Cough & Chest
Congestion**

DM

**DEXTROMETHORPHAN HBr
(Cough Suppressant)
GUAIFENESIN (Expectorant)**

Relieves:

- ▣ **Chest Congestion/Mucus**
- ▣ **Cough**

Non-Drowsy

**grape
flavor**

**4 FL OZ
(118 ml)**

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)			GUAIFENESIN	100 mg in 5 mL
Inactive Ingredients				
Ingredient Name				Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	PURPLE (purple)		Score	
Shape			Size	
Flavor	GRAPE (grape)		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8715-10	1 in 1 CARTON	07/01/2014	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part341	07/01/2014	

Labeler - Richmond Division of Wyeth (829390835)